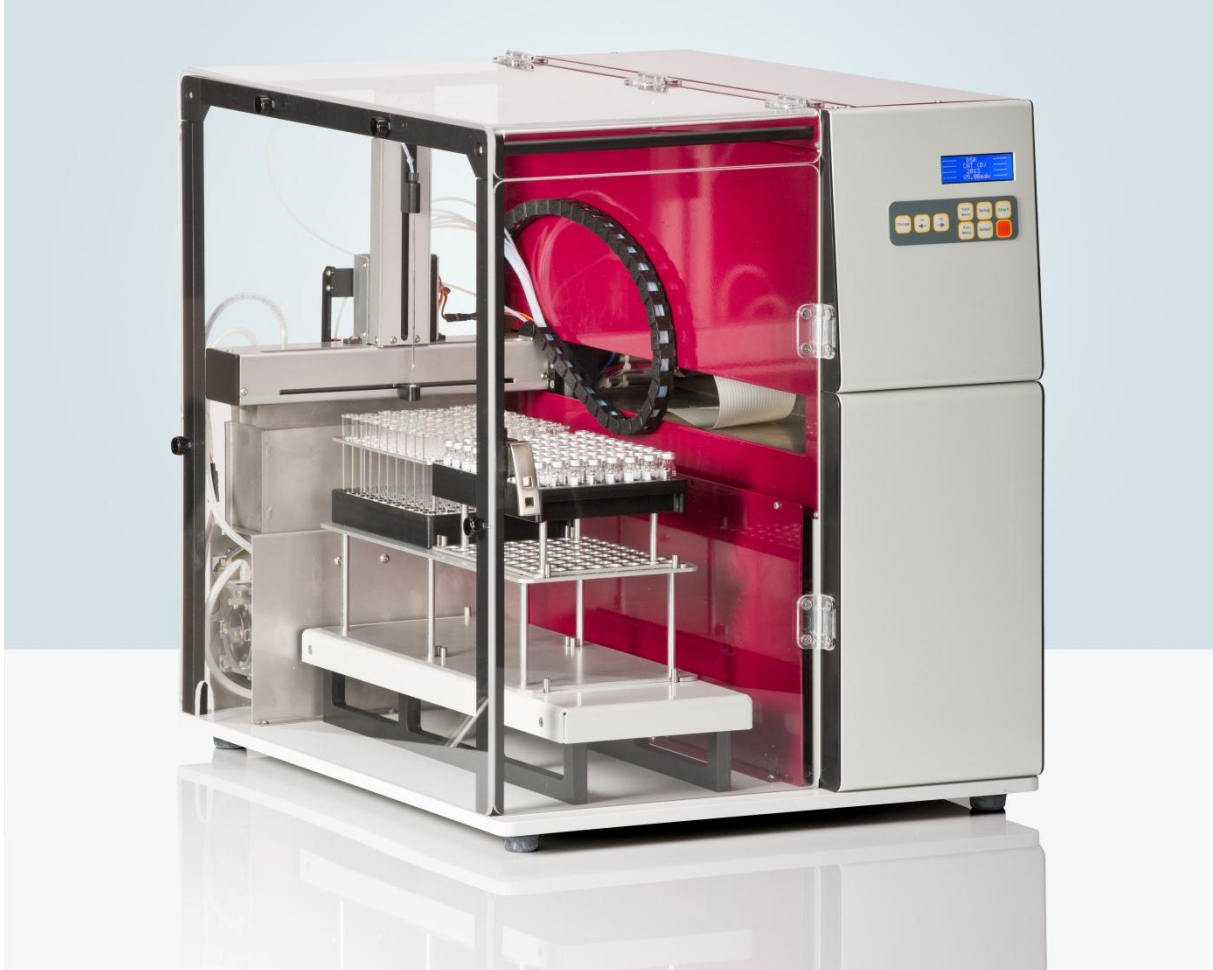
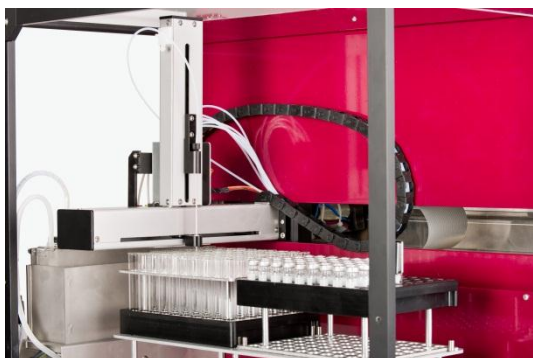


DSR-M – Dissolution Sampling Robot



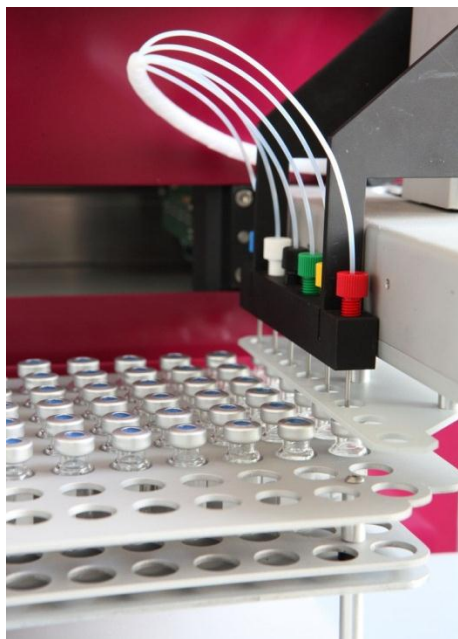
The DSR-M dissolution sampling robot is designed specifically for the sample transfer and sample processing from a six to twelve vessel dissolution bath. This unique versatile instrument allows samples to be collected over very short time intervals. The DSR-M can be equipped to collect, dilute or process samples for following UV-Visible or HPLC measurements. It can also be used for dissolution medium replenishment to conform to USP/EP volume loss rules.



Manual sampling from a dissolution test instrument is not only time consuming but also limits the reproducibility and is close to impossible if sustained release products have to be analyzed over prolonged time periods. The Pharma Test DSR-M provides a neat solution for this automation procedure.

Up to 20 sampling cycles can be run (10 if dilution is enabled). These are collected in two racks inside the DSR-M. The second rack is used either for sample collection or for sample processing, such as dilution. The unique rack design allows the user to use standard open vials or septa closed HPLC vials with the same rack.

Automated Sampling



To offer the highest volume precision, between six and thirteen piston pumps are used for sample removal and media refilling (optional), one dedicated pump for each channel. No time consuming pump calibration is needed. The advanced design of the system means that it is always ready for operation. The pumps are integrated into the DSR-M as a compact CAT-M pump module.

The sample preparation station, Z-arm and needle, can be used to dispense into septa sealed HPLC vials or dilute the samples for later UV/VIS analysis. Keeping the samples in sealed vials helps to avoid evaporation, especially if sustained release samples are tested.

The DSR-M can be connected to a Pharma Test PTWS-series and PT-DT70 dissolution bath. If the DSR-M is connected to a PTWS 310/610/1210 or D610 system the sampling probes are connected to the EPE auto sampling manifold. The motorized EPE lowers the sample probes into the corresponding

sampling position which can be set for either 500 or 900ml total media volume. Sampling cycle information is programmed directly at the dissolution bath using the method filing system. When a test is started either a trigger signal or the program file at the manual keypad of the DSR-M starts the sampling pumps inside the DSR-M so that the pre-set volume is withdrawn and dispensed into the vials or tubes inside the sample rack holder. Only one sample tubing line is required from the dissolution tester via the sampling manifold as all liquid sampling and refilling is made through the same tubing line by the CAT-MRM module (optional). So there is no need for extra return tubing for refilling.

If the DSR-M is equipped with the auto-media refilling option (CAT-MRM pump module), the refill cycle starts immediately after the sampling cycle is completed. After sampling and refilling is complete, the EPE sampling manifold is moved out of the dissolution medium and remains outside until the start of the next cycle. The X-Y-Z driven sampling arm holds the cannulas or piercing needles used to dispense the collected media into open vials or septa-sealed HPLC vials. The tubing installation is done using colour coded connectors for easy identification of the corresponding channel and kept as short as possible.



Filtration and MFC-12

Filtration of the collected samples can be done using 5 to 20 micron filter tips which are attached to the sampling probes and also using the MFC-12 manual filter changer which is integrated into the DSR-M tubing and may hold round filters from 1 to 0.45 micron. Since these round filters pass liquid in one direction only, an additional DSR-MVS valve station is required to create a bypass for the return flow.

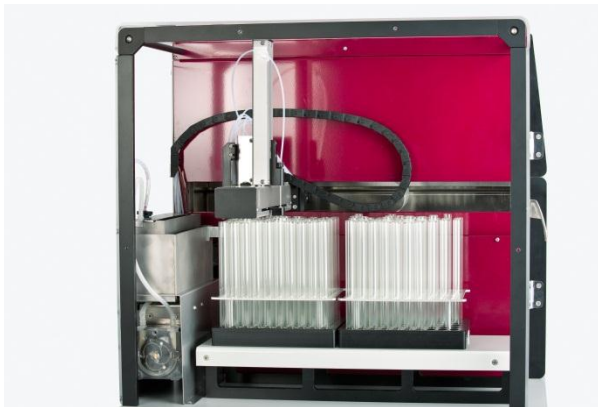


Programming

The sampling time information is set-up as a testing method using the method filing program of the PTWS dissolution bath connected. This includes also the EPE sampling probe control of the required immersion depth and dispensing time inside the dissolution media.

Sampling volume, dilution factor, refilling option, vial and rack type are programmed at the DSR-M itself. The data is filed and can be recalled at any time. Prior to the start of a run the operator enters product information such as a batch or lot number. The tablets are dropped simultaneously using a manual or automated tablet-drop magazine available for the PTWS 310/610/1210/D610 and PT-DT70 instruments.

Dilution of Sampled Media



If dilution of sampled media is required the DSR-M will use one of the two racks to collect the samples from the dissolution vessels and the second one will hold empty vials into which the diluted media will be dispensed. When sampling is finished the DSR-M will start to dilute. It will take the volume which needs to be diluted from the sampled media dispense it into the empty vials and add the diluent while mixing both using air. All vials are treated the same time in either open or septa-sealed vials. The DSR-M racks are installed on a tray that can be moved out of

the DSR-M easily to transfer the vials and to fill up the rack with new empty vials or glass tubes.

The DSR-M is completely enclosed by transparent acrylic glass to protect the operator from the moving arm and the samples from any external source.

The Piston Pumps



Unlike most systems the DSR-M does not use syringes but valve-less piston pumps. These pumps do not need any time consuming pre-filling and emptying cycles and change of valve positions. Also the dead volume is much smaller compared to conventional syringes and valve installations.

A rinsing valve is connected to each sampling and refilling valve to clean them using fresh diluent or media to avoid clogging due to the recipients inside the collected media. Fast

coupling systems allow the change of each individual pump head whenever this should become necessary. There are no wear and tear parts inside the pumps needing to be replaced; the precision is kept for the total life time.

Accessibility and Cleaning



All parts of the Plexiglass compartment can be easily opened or removed for cleaning.

The sample racks are stored on a drawer and the racks can be taken out of the system quickly.

Advantages

Some of the highlights the DSR-M offers are:

- Automates the taking of samples, the most labor intensive stage of a dissolution test
- Automated sampling eliminates human errors as equal sampling times and standardized solvent transport offer high reproducibility
- Flexible, modular design to allow auto media refill, dilution and transfer into sealed vials for six to twelve station dissolution baths
- The CAT-MRM module eliminates the need for separate refilling tubing lines
- Using the MFC-12 0.45 micron round filter can be exchanged easily and quickly between runs
- Small footprint due to auto sampler design with integrated pump module
- All moving parts are behind transparent enclosure to guarantee user safety

Features

The main features of the DSR-M are:

- Features valve free piston pumps for high precision
- Modular design to allow auto media refill, dilution and transfer into sealed vials for six to twelve station dissolution baths
- Up to 20 sampling cycles (10 cycles with dilution)
- Less than 1% transfer error
- Supports 0.45 micron filtration using MFC-12 manual filter changer and DSR-MVS valve station
- Sampling sequences are programmed directly at the Pharma Test dissolution bath
- Stand-alone mode available to support third party dissolution baths

Standard Scope of Supply

The DSR-M comes ready to use with the following standard scope of supply:

- DSR-M instrument with integrated CAT-M piston pump module
- Comprehensive documentation folder including:
 - User manual
 - IQ documentation
 - OQ documentation
 - Instrument logbook

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

- CAT-DM dilution and sample transfer module
- MFC-12 manual filter changer
- DSR-MVS valve station

Technical Data

Parameter	Specification
Number of Sampling Cycles	Up to 20 samples from a maximum of 13 vessels
Sampling Volume	1.0ml to 15.0ml
Accuracy	< 1% transfer error
Flow Rate	Minimum 0.15ml/min. Maximum 20.0ml/min.
Media Refilling	Using additional piston pumps (CAT-RM module, optional)
Sample Processing	X-Y-Z arm with septum piercing needle (optional)
Dilution Factor	Maximum 1:100
Display	Backlit LCD
Data Entry	Function keys
Materials Used	All wet parts: 99.7% Al ₂ O ₃ , Teflon or PEEK
Tubing	1.0mm ID to 1.6mm OD FEP or PTFE (not included in supply scope)
Dispensing Probe Positioning	± 0.8mm
Sample Processing Probe	± 0.5mm
Repeatability	± 0.3mm
Interface	RS232 port, analogue signal I/O port
Power	110/230 Volt, 50/60 Hz
Packaging Dimensions	Approx. 120cm x 80cm x 75cm (D x W x H)
Net Weight	Approx. 49kg
Gross Weight	Approx. 64kg
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included